

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
LAURA A. CORUZZI  
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NEW YORK, NY 10036

REFERRED TO  
REC'D

AUG 22 2001

Pennie & Edmonds  
O.K. for filing

## PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference

10165-006-22

Date of Mailing  
(day/month/year)

16 AUG 2001

REPLY DUE

within 1 months/days from  
the above date of mailing

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US00/10019 /

13 April 2000 (13.04.2000)

13 April 1999 (13.04.1999)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 38/00; C07K 14/00 and US Cl.: 530/326, 350; 514/2

Applicant

KENNETH S. WARREN LABORATORIES

*Response to Written Opinion - 9/16/01*

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13 August 2001 (13.08.2001).

Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231  
Facsimile No. (703)305-3230

Authorized officer

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**I. Basis of the opinion****1. With regard to the elements of the international application:\***☒ the international application as originally filed☒ the description:

pages 1-36, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☒ the claims:

pages 37-40, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages 1-17, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☐ The amendments have resulted in the cancellation of:**☐ the description, pages NONE \_\_\_\_\_☐ the claims, Nos. NONE \_\_\_\_\_☐ the drawings, sheets/fig NONE \_\_\_\_\_**5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International Application No.  
PCT/USC 0019

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>1-24</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-24</u>	NO
Industrial Applicability (IA)	Claims <u>1-24</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-24 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 4,806,524 in view of Grimm et al. (1990). U.S. Patent No. 4,806,524 discloses preparations of EPO in the presence of stabilizers (column 3, Table). U.S. Patent No. 4,806,524 does not teach methods of administration of EPO. Grimm et al. teaches a method of treatment of brain dysfunction in humans by administration of EPO (page 483, Figure 3). Therefore, it would have been obvious to use the EPO preparations disclosed in U.S. Patent No. 4,806,524 in a method of administration to a mammal to improve brain function.

----- NEW CITATIONS -----  
NONE

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.